REMARKS

Claims 1-10 remain in the application for further prosecution. Claims 11-13 were withdrawn from consideration after an election of Claims 1-10 without traverse. Therefore, Claims 11-13 have been cancelled and may become the subject of a subsequent divisional application. Claim 1 has been amended to distinguish the Columbus reference.

Claims 1-3 and 8 have been rejected under 35 U.S.C. 102(b) as anticipated by Columbus (U.S. 4,233,029). Such a conclusion could only be reached if the elements of Claim 1 are given an overly broad interpretation. Although the PTO rule requires that claims be given a broad interpretation in applying references, it is also the rule that claims should be interpreted with regard to the understanding of one skilled in the art. It is the Applicant's view that Columbus should not be considered to teach all of the structure claimed, especially after the above amendments.

First, while an inlet port is shown by Columbus, his device contains no capillary passageway in fluid communication between the inlet port and an inlet chamber. Even if the walls of the Columbus inlet port are considered a capillary passageway, the space between his opposed surfaces cannot be considered an enclosed chamber, since it is clear that liquid is to flow out at all four edges. Columbus describes a device intended to provide controlled multidimensional flow with a predetermined peripheral configuration (see Claim 1). In other words, liquid added to the inlet port flows across the entire surface as directed by sets of grooves placed at an angle to each other. The present microfluidic device is clearly different, since an enclosed unidirectional capillary passageway connects the inlet port to the enclosed inlet chamber. Columbus teaches the opposite approach, as he directly states at column 6, lines 31-34, "the multidirectional flow achieved by the device as described is the overall flow occurring in two or more non-aligned directions as primarily distinguished from unidirectional flow." From the illustrated application of the Columbus device in Fig. 9, it is obvious that the flow was intended to direct liquid out of the edges of the two-layer Columbus device. Claim 1 will be compared with Columbus in the following table, in which the differences will be made clear.

Claim 1	Columbus
A microfluidic device for assaying a liquid biological sample of 20 μL or less comprising:	o Columbus may be considered a microfluidic device, although it uses drop volumes between 5 and 1000 μL (column 4, lines 45-47), which relate to the purpose of the Columbus device. That is, Columbus spreads his sample over the space between two surfaces, rather than filling an inlet chamber. One would expect that Columbus would employ liquid volumes significantly greater than 20 μL.
(a) an inlet port for receiving said sample;	o Columbus does have an inlet port 26 for receiving a sample.
(b) an enclosed unidirectional capillary passageway in fluid communication with said inlet port;	o Columbus's "liquid access aperture 26" is an inlet port and not a capillary passageway. Columbus requires that surfaces 16 and 18 are wetted and transport the liquid sample by capillary action. The inlet port 26 is said to be sized to allow the sample drop to fill the port 26 and the space between the grooved surfaces 16 and 18. The total volume is said to be between 5 and 1000 μL. Note that Columbus says "aperture 26 has a configuration that is not too small to permit this" (i.e. provide wetting of the surfaces 16 and 18). In view of the space to be filled, it cannot be concluded that inlet port 26 is a capillary passageway. Fig. 2 shows a large drop placed on top of surface 24, which is drawn into the space between the two grooved surfaces by capillary action.

(c) an enclosed inlet chamber in fluid communication at one side thereof with the enclosed unidirectional capillary passageway of (b);	o Columbus's space between surfaces 16 and 18 is not enclosed, since it must be open at the edges to allow air to be expelled (see column 6, lines 13-20). The flow of liquid is not unidirectional in Columbus, as he concedes at column 6, lines 31-34. Furthermore, Columbus design requires entry from the middle in order to uniformly distribute liquid in all possible directions.
thereby permitting said sample to flow into said inlet chamber;	o Columbus has an inlet chamber only insofar as it is a space, but not as an <u>enclosed</u> chamber, which requires that the liquid be confined within the chamber. Columbus indicates at column 10, lines 1-7 that the sample liquid is distributed at the entire edge 20 or 22. Thus, Columbus's <u>chamber</u> does not correspond to the chamber disclosed by the Applicants.
said inlet chamber containing means for uniformly distributing said sample across said chamber and, displacing air from said chamber at a side opposite the entry of said capillary passageway;	o Columbus provides means for distributing liquid across his "chamber", but distributes 360° from a central location and not from one side of the chamber to an opposite side. Air is displaced at each edge of the space defined by 16 and 18 in Columbus. Columbus should not be considered to distribute liquid unidirectionally, since he teaches that liquid flows along the grooves and jumps over the edges so that the liquid moves in all directions, depending on the orientation of the pair of grooves on any given devices. (see Figs. 4-6).
and (d) at least one vent passageway for removing air displaced by said liquid sample at a side opposite the entry of said capillary passageway.	o Columbus does not use a vent passageway, but merely allows air to be purged at all the four edges of his device. Air is not removed from a side opposite an entry of the liquid.

That the Examiner gives unduly broad reading of the Applicant's claims also may be seen by considering whether they would be infringed by Columbus's device.

Claim 1	Columbus
o A microfluidic device for assaying a liquid biological sample of 20 μL or less comprising:	o If Columbus's device is assumed to employ much more than 20 μL typically, it would arguably not infringe.
o an inlet port for receiving said sample	o Columbus does have an inlet port 26 and would infringe this element of the claim.
o an enclosed unidirectional capillary passageway in fluid communication with said inlet port;	o Columbus opening 26 if considered an inlet port, would be contended to not include a capillary passageway, since at most one would have to consider the thickness of surfaces 24 to be a capillary passageway, which is not unidirectional. Further, based in the description in Kellogg, it is likely that opening 26 would be too large to provide capillary forces.
o an enclosed inlet chamber in fluid communication at one side thereof with the enclosed unidirectional capillary passageway of (b)	o Columbus would contend that his open-sided device was not an enclosed inlet chamber, nor did his space receive fluid at one side from his inlet 26.
o thereby permitting said sample to flow into said inlet chamber.	o Columbus would argue that his parallel grooved surfaces do not permit liquid to flow in, but instead draw liquid in by capillary forces.
o said inlet chamber containing means for uniformly distributing said sample across said chamber and, displacing air from said chamber at a side opposite the entry of said capillary passageway;	o Columbus would point out that his inlet 26 is centrally located and not from one side, so that liquid was distributed in many directions. Similarly, air is purged from each of the edges, not from a vent on a side opposite the liquid entry.

o and (d) at least one vent passageway for removing air displaced by said liquid sample at a side opposite the entry of said capillary passageway.	o Columbus would contend that his purging of air at all four edges of his device could not be considered a vent passageway or four vent passageways. In particular, that by opposing grooved surfaces, air is moved all directions at once, its flow is not directed, as is the liquid flow.

The Examiner considers that, in Claim 8, blood anti-coagulant is deposited in the inlet chamber to be a process or intended use limitation. Applicants disagree with his interpretation. A device according to Claim 1 includes the possibility that it could be of any color for example. Then, a dependent claim that states that the color is blue is a structural limitation, not just one of intended use. Similarly, if a device includes a blood anti-coagulant, it infers that the device is to be used with blood, but it is part of the device. There is no suggestion that Columbus's device would, or could, contain blood anti-coagulant.

Claims 1-3 and 8-10 have been rejected also under 35 U.S.C. 102(b) as anticipated by Columbus, U.S. 4,618,476. Columbus's '476 device is significantly different from his '029 device. However, one skilled in the art would not find the Applicant's invention in the '476 patent. The Examiner refers to Fig. 16, described at column 7, lines 15-38, which is a device intended to allow two liquids to flow side-by-side without mixing. The liquids are introduced separately through inlet ports 410 and travel along the right and left sides of transport zone 30g. The ribs are <u>not</u> used just to distribute liquids across the chamber, as the Examiner states, but are used to remove air from the transport zone (see column 4, lines 1-5 and 29-33). Columbus brings the two liquids in contact with ion-selective electrodes (ISE) disposed along the passage through which the liquids pass. Columbus sums up at column 7, beginning at line 60 "As a result, two dissimilar but misible liquids introduced into zone 30g via apertures 410 will flow side-by-side, along serpentine paths, producing a junction that approximately bisects apertures

42C and is substantially free of convection mixing. Portions of each liquid, one of which is a reference liquid, are withdrawn through apertures into contact with their respective ISE's, ..."

Thus, Columbus '476 does not lead one to introducing one liquid sample into an inlet port connected with an enclosed unidirectional passageway to an enclosed inlet chamber which contains means for uniformly distributing the sample across the inlet chamber. Instead, Columbus '476 teaches in Fig. 16 a device for measuring the properties of two liquids flowing concurrently in his device, but without mixing, which would defeat the purpose of the device.

Claim 1 will be compared with Columbus '476 in the following table, in which the differences will be made clear.

Claim 1	Columbus '476
A microfluidic device for assaying a liquid biological sample of 20 µL or less comprising:	o Fig. 16 discloses a device for handling two liquids flowing concurrently through the device without mixing (column 7-8). Although the specific liquid volumes are not stated, it is likely that the large amounts of liquid of Columbus '029 (5-1000 µL) are involved, rather than one liquid sample of 20 µL or less as in the Applicant's specification.
(a) an inlet for receiving said sample	o Fig. 16 contains two apertures (410) not one inlet for one sample.
(b) an enclosed unidirectional capillary passageway in fluid communication with said inlet port;	o Consistent with the two apertures (410). Fig. 16 shows two passageways in fluid communication with the inlet apparatus.
(c) an enclosed inlet chamber in fluid communication at one side thereof with the enclosed unidirectional capillary passageway of (b);	o Capillary transport zone 30g maintains concurrent flow of two liquids, that flow out through slots 450 to their respective ion-selective electrodes. Thus, rather than providing uniform distribution of the two liquids across the transport zone 30g. They are kept separate.

thereby permitting said sample to flow into said inlet chamber;	o As noted above, the flow of <u>two</u> liquids are concurrent, not mixed, since the objective of the design of the device in Fig. 16 is to deliver the liquids to their respective ion-selective electrodes through slots 450.
said inlet chamber containing means for uniformly distributing said sample across said chamber and, displacing air from said chamber at a side opposite the entry of said capillary passageway;	o The flow of two liquids, which are kept separate, are not distributed uniformly across the transport zone 30g. Where air is purged in Fig. 16 is not clear. In other figures it appears that air is purged through vents at the top of the transport zone, but in Fig. 16 those vents are not mentioned. The only air vent mentioned is 480 at the end of a waste chamber 470.
and (d) at least one vent passageway for removing air displaced by said liquid sample at a side opposite the entry of said capillary passageway.	o As noted above, the vent in the Applicant's chamber's at the end of their inlet chamber. The only vent identified in Fig. 16 is 480 at the end of waste chamber 470, <u>not</u> in the transport zone 30g.

Claim 8 has again been considered a process or intended use limitation. As discussed above, the Applicants believe the presence of a blood anti-coagulant is more properly considered part of the structure as claimed, rather than a process or intended use.

Claims 4-6 have been rejected under 35 U.S.C. 103(a) as unpatentable (i.e. obvious) over Columbus '029 in view of Peters, U.S. 6,296,126 B1, the later cited for the use of wedge-shaped cut-out structures. Peters is a co-inventor in the present application, and his patent was cited in paragraph 0037 of the published application (or page 11, line 17). Claims 4-6 are dependent from Claim 1 and if, as the Applicants contend, Claim 1 is distinguished from Columbus and patentable, then Claims 4-6 should also be allowable. Futhermore, Peters does not disclose his posts to distribute liquid uniformly in parallel to the posts, but instead uses the v-shaped grooves as channels for the liquid.

Claim 7 has been rejected under 35 U.S.C. 103(a) as unpatentable over Columbus '029 in view of Bedingham et al, U.S. 6,734,401 B2, cited for disclosing a tapered inlet port to engage a pipette tip. As with Claims 4-6, Claim 7 should be allowable if Claim 1 is patentable over Columbus.

In view of the above remarks the Examiner is urged to allow the amended claims remaining in the application. If further amendments are believed necessary, the Examiner is invited to contact the Applicant's attorney at the telephone number provided below.

Respectfully submitted,

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Date

Harold N. Wells
Reg. No. 26,044
Jenkens & Gilchrist, P.C.
225 West Washington Street, Suite 2600
Chicago, IL 60606-3418
Attorney for Applicants
Tel.: (312) 425-8610